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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/519,594

12/28/2004

David Cavalla

GJE-6758

2624

23557

7590

07/27/2006

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EXAMINER

SOROUGH, LAYLA

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/519,594	<b>Applicant(s)</b> CAVALLA ET AL.	
	<b>Examiner</b> Layla Soroush	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 December 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/11/05</u> . | 6) <input type="checkbox"/> Other: _____  |

***Priority***

The Office Action is in response to the Preliminary Amendment filed December 28, 2004. This application is a 371 of PCT/GB03/02974 07/09/2003. Claims 1-7 are pending.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ninomiya et al. (US Pat. No. 4,695,568 –IDS), in view of Davies et al. (US Pat. No. 6,008,227).

Ninomiya et al. teaches a 4-(2-Fluorophenyl)-6-methyl-2-(1-piperazinyl)thieno[2,3-D]pyrimidine monohydrate hydrochloride in treatment of various depressions (see abstract; column 4, lines 9-11).

Ninomiya et al. does not specifically teach the compound to treat functional bowel disorder.

However, Davies et al. teaches, in the Background of the Invention, that antidepressant drugs are drugs that inhibit monoamine uptake mechanisms, through the dopamine, 5-HT, and norepinephrine transporters. Monoamine uptake blockers have also been useful in treatment of chronic pain (includes nociceptive pain), neuralgias

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(neuropathic pain), migraine, sleep apnea, fibromyalgia, and irritable bowel syndrome (functional bowel disorder) (column 1 lines 60-67 and column 2 lines 1-2), as recited in claims 1 and 2.

Therefore, it would have been obvious to one of ordinary skill in the art to use 4-(2-Flourophenyl)-6-methyl-2-(1-piperazinyl)thieno[2,3-D]pyrimidine in treating functional bowel disorder. The motivation to use 4-(2-Flourophenyl)-6-methyl-2-(1-piperazinyl)thieno[2,3-D]pyrimidine to treat functional bowel disorder is because of the teachings in Davies et al. that antidepressant agents used to inhibit monoamine uptake mechanisms are also useful in treating irritable bowel syndrome (functional bowel disorder). The skilled artisan would have reasonable expectation of treating irritable bowel syndrome (functional bowel disorder) using the antidepressant drug 4-(2-Flourophenyl)-6-methyl-2-(1-piperazinyl)thieno[2,3-D]pyrimidine.

Additionally, because the reference teaches the genus irritable bowel syndrome, the species diarrhea-predominant irritable bowel syndrome, alternating constipation/diarrhea irritable bowel syndrome, and constipation-predominant irritable bowel syndrome of claims 3, 4, 6 and 7 are rendered obvious by the teachings of the prior art. The reference teaches patients in general, therefore, the limitation of claim 5, "wherein the patient is female" is rendered obvious by the prior art reference.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to

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identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-7 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 5-11 of copending Application No.10617847. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### ***Conclusion***

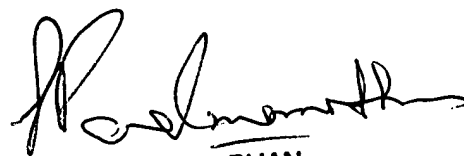
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'S. Padmanabhan', with a stylized, cursive script.

**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**